

REMARKS

Claim Rejections – 35 USC §103

Claims 54-70 and 75-79 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,454,365 to Bonutti, and claims 54-58, 64-70 and 74-76 have been rejected as being unpatentable over U.S. Patent No. 5,885,258 to Sachdeva.

Independent claims 54, 59 and 75 are currently pending in the subject application and each recite, among other elements and features, an elongate member including a deformable distal portion having an initial/relaxed configuration for placement adjacent a spinal structure, and an expanded/stressed configuration wherein the deformable distal portion is outwardly deformed to define “at least one but no more than two transverse projections”, with “each of said transverse projection arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis . . . such that at least a portion of the spinal structure is uniaxially displaced along said transverse axis”.

The final Office Action admits that Bonutti and Sachdeva fail to disclose an instrument including two oppositely and equally spaced transverse projections that extend in a uni-axial direction along a single transverse axis. Instead, the Office Action asserts that each of these references “discloses a plurality of projections equally or unequally spaced apart”. (Page 4, lines 5-8 page 6, lines 12-15). Nevertheless, the Office Action asserts that “[w]hile Bonutti does not explicitly teach two oppositely spaced transverse projections, Bonutti does disclose that the number of projections may vary and that they may be spaced equally . . . in order to provide varying expansion” and that “[i]t would have been obvious . . . to construct the Bonutti device with two, oppositely spaced projections in view of Bonutti’s own disclosure . . . to provide varying expansion.” (Page 4, lines 10-15; citations omitted). Similarly, the Office Action asserts that “[w]hile Sachdeva et al. does not explicitly teach two oppositely spaced transverse projections, Sachdeva et al. does disclose that the amount of slots, and consequently projections, may vary depending on the intended function of the device” and that “[i]t would have been obvious . . . to construct the Sachdeva et al. device with two, oppositely spaced projections in

view of Sachdeva et al.'s own disclosure . . . depending on the intended function.” (Page 6, lines 16-22; citations omitted).

With regard to Bonutti, disclosed therein is a mechanically expandable retractor for use in arthroscopic surgery. The retractor has an expanding portion at its distal end for expanding sub-surface tissue, with the expanding portion including a series of radially expanding arms that are positioned circumferentially about the retractor to expand the sub-surface tissue to provide a working space between adjacent arms. (See Abstract). As shown in Figure 1 and 2, the retractor 10 includes an inner retractor body 12 and an outer retractor sleeve 14, with the retractor sleeve 14 having an expanding portion 60 that “includes a plurality of circumferentially spaced expanding arms 62. Adjacent arms 62 define between them a series of slots 64. The expanding portion 60 . . . has eight equally spaced arms 62 over a 360° range. It should be understood that the present invention contemplates that any different number of arms can be used, and they can be spread equally or unequally over a different circumferential extent, in order to provide varying or eccentric expansion.” (See column 4, line 63 to column 5, line 4). Similar embodiments of retractor instruments are illustrated in Figures 6-30, each including an outer retractor sleeve that is also provided with multiple circumferentially spaced expanding arms that are positioned over different circumferential extents of the outer sleeve.

Even assuming *arguendo* that the circumferentially spaced expanding arms 62 could be construed to comprise transverse projections, each embodiment of the Bonutti device clearly includes more than two circumferentially spaced expanding arms 62. Additionally, as admitted in the Office Action, each of the expanding arms 62 is not “arranged along a single transverse axis”, and do not extend “in a uni-axial direction along with said single transverse axis” such that at least a portion of a spinal structure is uniaxially displaced along the single transverse axis, as recited in independent claims 54, 59 and 75. To the contrary, the expanding arms 62 are arranged along multiple transverse axes and extend in multiple radial directions that are clearly not aligned with a single transverse axis. Accordingly, Bonutti fails to satisfy each of the elements and features recited in independent claims 54, 59 and 75.

Moreover, the Applicant submits that one of ordinary skill in the art would not be motivated to modify the instrument disclosed in Bonutti to include no more than two expanding arms 62, and to arrange the expanding arms 62 along a single transverse axis so as to extend in a

uni-axial direction. It is well established that “[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. . . . The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure.” MPEP §2142 (citing *In re Vaeck*, 20 USPQ.2d 1438 (Fed. Cir. 1991)). Additionally, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” MPEP §2141.02 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983)).

As indicated above, Bonutti discloses an arthroscopic retractor including expanding arms 62 positioned circumferentially about the retractor “for expanding sub-surface tissue . . . to provide a working space between adjacent arms.” (See Abstract). As shown in Figures 6 and 7, “the expanding arms 62 are disposed irregularly circumferentially around the retractor to provide an increased working space or operating area between particular pairs of expanding arms 62. . . . An enlarged working space 81 is formed between the arm 82 and the arm 84 of the sleeve 14a.” (See column 5, lines 58-61; emphasis added). The working space 81 thereby provides increased visualization of the surgical site, and also provides an unobstructed operating space/area to provide a circumferential passageway for surgical instruments to operate on sub-surface tissues aligned with the working space 81 between adjacent pairs of the expanding arms 62. As should be appreciated, positioning of each of the expanding arms 62 “along a single transverse axis” so as to extend “in a uni-axial direction along with said single transverse axis” would not form a circumferential visualization space or operating area between adjacent pairs of the expanding arms 62, as specifically taught by Bonutti. Although alignment of the expanding arms 62 along a single transverse axis may be used to expand sub-surface tissue, such a configuration would not provide an unobstructed working space/area between adjacent arms 62, as taught by Bonutti. To the contrary, such a configuration would obstruct viewing of the surgical site, and would not provide a circumferential passageway between adjacent pairs of the arms 62 to receive surgical instruments to operate on sub-surface tissues. Furthermore, in order to increase visualization of the surgical site and to allow for an unobstructed operating space/area to provide a circumferential passageway for surgical instruments to operate on sub-surface tissues aligned

with the working space 81 between adjacent pairs of the expanding arms 62, the Bonutti device must necessarily include more than two expanding arms 62.

Referring to Figures 22 and 23, illustrated therein is a typical use of the retractor device which is disclosed as follows:

The expanding arms 62 move radially outwardly to create a working or operating area 198 adjacent the ligament 192. . . . Because of the controlled expansion of the retractor 160, the median nerve 194 is shielded from the operating area. Tools and an arthroscope may be passed through the opening 162 into the operating area 198, while the median nerve 194 and other tissues such as tendons 200 are safely shielded from the operating area 198. Accordingly, by use of the retractor 160, the surgeon is provided with an enlarged open area in which he can work on the ligament 192, and at the same time he has protected the median nerve 194 from the operating area. The surgeon has full visualization and working of the entire space, not a limited vision area as with other systems. (See column 9, lines 11-33).

As should be apparent, if the Bonutti device were limited to two expanding arms 62 arranged “along a single transverse axis” and extending “in a uni-axial direction along with said single transverse axis”, the expanding arms 62 would not form a circumferential visualization space or operating area between adjacent pairs of the expanding arms 62. The Bonutti device would therefore not function as intended to provide full visualization of the surgical site via the working or operating area 198 between the expanding arms 62. When the teachings of Bonutti are taken as a whole and considered in their entirety, one of ordinary skill in the art would not limit the Bonutti device to “no more than two” expanding arms 62 arranged “along a single transverse axis” to extend “in a uni-axial direction”, for to do so would not provide the circumferential visualization space or operating area between adjacent expanding arms 62. Accordingly, one of ordinary skill in the art would not be motivated to modify the Bonutti device to arrive at the invention recited in independent claims 54, 59 and 75. As a result, a *prima facie* case of obviousness is not apparent with regard to the rejection of the pending independent claims under 35 U.S.C. §103(a) in view of Bonutti. The Applicant therefore submits that independent claims 54, 59 and 75 are patentable over Bonutti.

With regard to Sachdeva, disclosed therein are a number of medical instruments that include distal portions which are deformable to perform various functions. Illustrated in Figures 1A-1D is a tube 11 having four slots 12 that are provided to create a balloon-shaped structure

that can be used as a retrieval basket to capture small particles 14. Figure 2 illustrates a tool for dilation of a tubular-shaped vessel 24, where the tube 21 and the axial segments 22 determine the magnitude of the dilation force F exerted against the inner wall of the vessel 24. Figure 3 illustrates a tubular reamer including multiple cutting elements or edges 32 extending along the tube 31 to cut and remove material from the inner wall of an artery or other tubular cavities via rotation of the tube 31. Figures 4-11 disclose similar types of expandable tubular devices including an expandable tube portion, the details of which have already been set forth in Applicant's response to a previous Office Action.

Even assuming *arguendo* that the axially-extending slots formed along the distal ends of each of the tubular instruments could be construed to form transversely projecting segments, each of the instruments disclosed in Sachdeva clearly includes more than two transversely projecting segments. Additionally, as admitted in the Office Action, each of the segments are not "arranged along a single transverse axis", and do not extend "in a uni-axial direction along with said single transverse axis" such that at least a portion of a spinal structure is uniaxially displaced along the single transverse axis, as recited in independent claims 54, 59 and 75. To the contrary, the transversely projecting segments are arranged along multiple transverse axes and extend in multiple radial directions. Accordingly, Sachdeva fails to satisfy each of the elements and features recited in independent claims 54, 59 and 75.

Moreover, one of ordinary skill in the art would not be motivated to modify the instruments disclosed in Sachdeva to include no more than two transversely projecting segments, and to arrange the transversely projecting segments along a single transverse axis so as to extend in a uni-axial direction. As indicated above, "[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings", and "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (Citations omitted). Notably, Sachdeva discloses multiple embodiments of tubular instruments that are each provided with four axially-extending slots that correspondingly form four transversely projecting segments positioned uniformly about the circumference of the tube. However, Sachdeva fails to disclose or suggest that any of the instruments could be modified to include

“no more than two” of the transverse segments, or to arrange each of the segments “along a single transverse axis” to extend “in a uni-axial direction”. Additionally, the Applicant submits that providing each of the instruments with multiple transversely projecting segments (i.e., more than two) spaced circumferentially about the tubular member is not mere happenstance, but instead constitutes an important design feature that is critical to the particular functions of the disclosed instruments.

With regard to the retrieval instrument illustrated in Figures 1A-1D, as should be appreciated, in order to securely capture and retain the particle 14 within the interior of the slotted portion of the tube 11, three or more axially-extending segments are required. As should also be appreciated, providing the tube 11 with axially-extending segments arranged along a single transverse axis would not maintain the particle 14 within the interior of the slotted portion of the tube 11. Indeed, such a design would allow the particle 14 to slide out from the open space between the axially-extending segments. With regard to the dilation instrument illustrated in Figure 2, in order to uniformly dilate the inner diameter of the blood vessel 24, multiple axially-extending segments spaced circumferentially about the slotted portion of the tube 21 are also required. Providing the tube 21 with no more than two axially-extending segments arranged along a single transverse axis would not uniformly dilate the vessel 24, but would instead result in stretching of the vessel wall in a single direction. With regard to the reamer instrument illustrated in Figure 3, in order to safely remove material or particles from the inner wall of an artery or other tubular cavities via the cutting edges 32, once again, providing multiple axially-extending segments spaced circumferentially about the slotted portion of the tube 21 are required. Indeed, providing the tube 31 with no more than two axially-extending segments arranged along a single transverse axis would not maintain the slotted portion of the tube 31 at a central location within the artery, which could in turn result in cutting too deeply into the inner arterial wall and possible severing the artery as the cutting edges 32 are rotated about the central axis of the tube 31. In order to reduce the risks associated with this potentially life-threatening condition, the reamer is provided with four axially-extending segments spaced uniformly about the circumference of the tube 21. With regard to the remaining instruments and devices illustrated in Figures 5-12, in order to securely maintain the slotted portion of the tube at the proper location within the tubular structure (see Figures 9A-9C and 10A-10C), the slotted

portion is similarly provided with multiple axially-extending segments spaced circumferentially about the slotted portion of the tube.

Since each of the devices and instruments disclosed in Sachdeva are contemplated for use in association with tubular-shaped anatomic structures, each of the instruments are provided with three or more transversely projecting segments arranged along multiple transverse axes and extending in multiple radial directions to closely conform with the inner diameter of the tubular-shaped anatomic structures. Therefore, when taken as a whole and considered in its entirety, one of ordinary skill in the art would not be motivated to modify the instruments and devices disclosed in Sachdeva to provide no more than two axially-extending segments arranged along a single transverse axis, as the resulting instrument would not adequately conform with the circular shape of the inner walls of the tubular-shaped anatomic structures, and would not securely maintain the instrument or device at the proper location within the tubular anatomic structure. As a result, a *prima facie* case of obviousness is not apparent with regard to the rejection of the pending independent claims under 35 U.S.C. §103(a) in view of Sachdeva. Accordingly, the Applicant submits that independent claims 54, 59 and 75 are patentable over Sachdeva. The Applicant further notes that claim 59 has not been rejected based on Sachdeva.

For at least the reasons set forth above, independent claims 54, 59 and 75 are submitted to be patentable over Bonutti and Sachdeva. The Applicant respectfully requests withdrawal of the rejection of independent claims 54, 59 and 75 and allowance of the same. Claims 55-58 and 64-74 depend either directly or indirectly from independent claim 54, claims 60-63 depend either directly or indirectly from independent claim 59, and claims 76-79 depend either directly or indirectly from independent claim 75. Accordingly, dependent claims 55-58, 60-74 and 76-79 are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims. However, further reasons support the patentability of the claims depending from independent base claims 54, 59 and 75.

For example, dependent claim 58 recites that “said expanded configuration defines a single pair of transverse projections arranged generally opposite one another along said single transverse axis”. Additionally, dependent claim 76 recites subject matter similar to that recited in dependent claim 58. However, as indicated above with regard to independent claims 54, 59

and 75, neither Bonutti nor Sachdeva disclose or suggest that any of the instruments or devices include a single pair of transverse projections arranged along a single transverse axis

Additionally, dependent claim 67 recites that the transverse projections are defined by a flexible strip of material having a predetermined shape “including a series of arcuate portions” to provide controlled transitioning to an outwardly buckled configuration. Dependent claim 70 further recites that the deformable distal portion defines a plurality of slots having a predetermined shape that is “at least partially comprised of an hour-glass shape” to provide controlled outward buckling of the transverse projections. Although the Office Action asserts that Bonutti and Sachdeva both disclose the features recited in dependent claims 67 and 70, this clearly does not appear to be the case. With regard to Bonutti, the distal end portion of the tissue retractor includes a series of rectangular-shaped slots 64 having a uniform shape and width, which in turn define a series of rectangular-shaped expanding arms 62. Bonutti fails to disclose or suggest that the expanding arms 62 include an arcuate portion, much less “a series of arcuate portions”, to provide controlled transitioning to an outwardly buckled configuration. Bonutti also fails to disclose or suggest that the slots 64 may be provided in non-rectangular configurations, much less “at least partially comprised of an hour-glass shape”. Similarly, with regard to Sachdeva, the instruments and devices are likewise provided with a series of rectangular-shaped slots having a uniform shape and width, which in turn define a series of rectangular-shaped segments of material. Sachdeva therefore fails to disclose or suggest that the segments of material include an arcuate portion, much less “a series of arcuate portions” to provide controlled transitioning to an outwardly buckled configuration. Sachdeva also fails to disclose or suggest that the slots 12 may be provided in non-rectangular configurations, much less “at least partially comprised of an hour-glass shape”.

CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 54-79. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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